Claim 11 was objected to under 37 CFR 1.75(c). This objection is respectfully traversed. Claim 11 and Claim 10 are not identical. In Claim 10, the lubricious coating is incorporated "onto" and in Claim 11, the coating is incorporated "into."

Claims 1-12 and 14-17 were rejected as anticipated by U.S. Patent Number 6,299,604 to Ragheb et al. (Ragheb). This rejection is respectfully traversed.

Ragheb discloses a coated implantable medical device. In specific embodiments, the medical device comprises a vascular device such as a stent. In one embodiment, one surface of the stent is coated with a bioactive material, and in another embodiment, a second bioactive material is attached to a second surface of the stent. Porous layers may be placed over the bioactive layers to precisely control the release rate of the bioactive agents. As set forth at column 8, lines 30-37, heparin (anti-coagulant) is affixed to the outer surface of the stent. In yet another alternate exemplary embodiment, the stent is coated with a first coating, then a bioactive agent and then the porous coating to control drug release. In the embodiments wherein the

stent comprises holes, the bioactive agent is placed in the holes and then coated with the porous layer.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention, as claimed in amended independent Claim 1, is directed to a local drug delivery device which comprises a medical device for implantation into a treatment site of a living organism, at least one agent in therapeutic dosages releasably affixed to the medical device for the treatment of reaction by the living organism caused by the medical device or the implantation thereof, and a lubricious material for preventing the at least one agent from separating from the medical device prior to implantation. The lubricious material is affixed to at least one of the medical device or a delivery system for the medical device. In newly added Claim

52, a water soluble powder is needed to prevent the agent from separating.

Ragheb discloses a porous layer dispersed over the therapeutic agent. Ragheb intends the layers to be separate. The porous layer controls the elution rate of the bioactive agent. Parylene or a parylene derivative may be deposited to change the pore size of the porous layer. The porous layer also serves to protect the bioactive layer during deployment of the device. In the claimed invention, a lubricious coating or a water soluble powder is used to prevent he agent from separating from the medical device. Ragheb discloses this porous layer, but this porous layer is not lubricious as set forth in claim 1, nor is it a water soluble powder as set forth in claim 52. The powder referred to in Ragheb is a powder form of the bioactive agent. Since Ragheb fails to disclose or even remotely suggest a lubricious coating or a water soluble powder, there can be no anticipation. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 13 was rejected as being unpatentable over Ragheb. This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Applicants respectfully submit that Ragheb fails to disclose or remotely suggest a lubricious material. Ragheb discloses polymers to protect bioactive agents and not lubricants such as

silicone or water soluble powders; accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-17 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 12-14, 17 and 28-36 of copending Application No. 09/962,496.

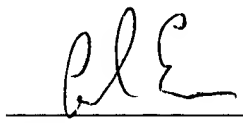
Applicants understand that this rejection is to alert Applicants that an actual rejection on the same ground may be issued if one of the applications ultimately issues. However, in light of the amendment to the claims of the present invention and any potential amendments made to the claims of the cited application, Applicants shall defer any arguments and/or actions until the applications actually issue.

Applicants would be willing to interview the present case if the Examiner so desires. Accordingly, the Examiner is invited to call the undersigned at (732) 524-2518 if such a call would facilitate the prosecution of this application.

A favorable action on the merits is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version With Markings To Show Changes Made."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend the claims as follows:

1. (Amended) A local drug delivery apparatus comprising:

a medical device for implantation into a treatment site of a living organism;

at least one agent in therapeutic dosages releasably affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or the implantation thereof; and

a lubricious material for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the lubricious material being affixed to at least one of the medical device or a delivery system for the medical device.

Please cancel Claim 9 without prejudice.

10. (Amended) The local drug delivery apparatus according to Claim [9]1, wherein the lubricious coating is incorporated onto the medical device.

11. (Amended) The local drug delivery apparatus according to Claim [9]1, wherein the lubricious coating is incorporated into the medical device.

12. (Amended) The local drug delivery apparatus according to Claim [9]1, wherein the lubricious coating is incorporated onto the delivery system for the medical device.

13. (Amended) The local drug delivery apparatus according to Claim [9]1, wherein the lubricious coating comprises a silicone-based material.

Please cancel Claim 14 without prejudice.

15. (Amended) The local drug delivery apparatus according to Claim [14]52, wherein the water soluble powder is incorporated onto the medical device.

52. (New) A local drug delivery apparatus comprising:

a medical device for implantation into a treatment site of a living organism;

at least one agent in therapeutic dosages releasably affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or the implantation thereof; and

a water soluble powder for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the water soluble material being affixed to at least one of the medical device or a delivery system for the medical device.